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| INFORMATION DISCLOSURE STATEMENT BY APPLICANT | | | | Application Number | 10/532,404 |
| | | | | Filing Date | 04/22/2005 |
| | | | | First Named Inventor | Merrill, William |
| | | | | Group Art Unit | 3751 |
| (use as many sheets as necessary) | | | | Examiner Name | Maust, Timothy Lewis |
| Sheet | 1 | of | 1 | Attorney Docket Number | 1054-003 |

| NON-PATENT DOCUMENTS | |
|----------------------|---|
| Examiner Initials | Include name of the author (in CAPITAL LETTERS), title of the article (when appropriate), title of the item (book, magazine, journal, serial, symposium, catalog, etc.), date, page(s), volume-issue number(s), publisher, city and/or country where published. |
| | FDA, "Guidance for Industry, Sterile Drug Products Produced by Aseptic Processing - Current Good Manufacturing Practice", August 2003, 34 pages |
| | FDA, "Guideline on Sterile Drug Products Produced by Aseptic Processing", June 1987, 45 pages |

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| Examiner Signature | | Date Considered | |
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*EXAMINER: Initial if reference considered, whether or not citation is in conformance with MPEP 609. Draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

¹ Unique citation designation number. ² Applicant is to place a check mark here if English language Translation is attached.

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